

the literature as a "reduced Heart Rate Variability" (HRV) is indicative of an abnormal condition without regard to its cause or nature, and constitutes a "Mortality Risk."

Submitted herewith is an article entitled "The Origin of Disease and Health - Heart Waves" that appear in Cycles - Vol. 46, No. 3, Dec 1996. The author of this article is Irving I. Dardik, M.D., Founding Chairman of the United States Olympics Sports Medicine Council, the applicant herein.

The article asks "Why does a decrease in heart rate variability (HRV) emerge as a single common risk factor for virtually all chronic diseases at all ages?" The present invention is addressed to this question.

The purpose of the exercise program set forth in claim 1 is to cause the patient's heart rate range (HRV) to approach a range that is normal for that patient, and in doing so to overcome his abnormal condition, whatever its nature and cause.

To this end, in the course of the program as the patient exercises, his heart pulse rate is continuously monitored, for the indicated pulse rate guides the program.

The patient is subjected "to a series of exercise-relaxation cycles in which in the course of each cycle the patient experiences a surge of energy causing his pulse rate to reach a peak value above said resting heart rate to a degree that depends on the patient's physical state, at which point the patient then relaxes and his heart rate because of a pendulum effect induced in the patient's heart, swings down from the peak value to a point below said resting heart rate to produce a spiked heart wave."

The pendulum effect is the key to the effectiveness of the program, for applicant has found that the human heart behaves in a manner similar to that of an oscillating pendulum in which the amplitude of oscillation depends on the force of the impulse which incites the pendulum into motion.

As shown in Fig. 2, the successive exercise-relaxation cycles produce a spiked heart wave that expands the heart beat range that runs from the rate at rest to the maximum rate resulting from stress.

The program is continued "until the patient's maximum pulse rate and resting pulse rate approach those of an individual having a normal heart rate range and free from the abnormal condition."

It will be seen in Fig. 2 that with the first surge  $S_1$  in the exercise cycle, the patient's pulse rate goes above the initial heart resting pulse rate  $R$ , and then falls below this initial resting rate. But because of the pendulum effect, with the second surge  $S_2$ , the pulse heart rate goes still higher above the initial heart resting pulse rate  $R$ , and with the third surge  $S_3$  yet still higher.

Heart rate variability (HRV) is the range extending from the heart rate at rest to the maximum rate produced by exercise activity, and HRV is the same as the range referred to in applicant's specification. As pointed out in the Circulation article previously submitted, HRV is influenced by various pathological factors. But regardless of the nature of the pathology or abnormal condition, if the patient has a "Reduced" HRV (i.e., a compromised heart rate range) the patient's "mortality" is at risk, and he may not survive.

Also previously submitted is an article by Moser et al. in the same issue of Circulation dealing with the "Prognostic value of heart rate variability with respect to survival."

A patient with reduced heart rate variability is not likely to survive, whereas a patient whose HRV has been expanded by the claimed exercise program stands a far better chance of surviving.

The Rejection:

The rejection of the claims under Section 103 as being unpatentable over Anderson in view of Dardik is clearly untenable.

Anderson, the primary reference, provides an exercise program for physical rehabilitation in which the intensity and duration of the workout are defined as independent variables for an exercise protocol in the course of which the patient's pulse rate is monitored. The training program (see claim 5, lines 1 to 19) consists of a series of exercise sessions over time "wherein the same exercise protocol is repeatedly used by the subject."

The nature of the protocol in Anderson is not such as to subject the patient to a series of exercise-relaxation cycles as set forth in claim 1 to expand the patient's HRV or heart beat range.

Dardik, the secondary reference, discloses biofeedback exercise technique for inducing relaxation to counteract the effects of stress. To this end the patient undergoes rhythmic exercise-relaxation cycles in the course of which the heart beat of the patient is monitored and displayed to the patient. The patient, by observing his changing heart

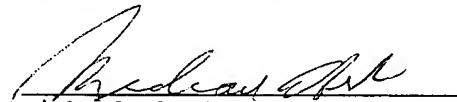
beat rate (biofeedback) is then able to reduce his state of stress.

The nature of the exercise cycles in the Dardik patent are not such as to induce a pendulum effect as set forth in claim 1 and to expand the patient's HRV.

Hence even if one were to modify the exercise protocol of Anderson so that it took the form of the rhythmic exercise program of Dardik, this would not recreate the claimed invention.

Accordingly, favorable action is respectfully requested.

Respectfully submitted,



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